UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE INSULIN PRICING LITIGATION	**Case No. 2:23-md-3080 (BRM)(RLS)** **MDL No. 3080** **Judge Brian R. Martinotti** **Judge Rukhsanah L. Singh** **ORAL ARGUMENT REQUESTED**

THIS DOCUMENT RELATES TO: Nos. 2:23-cv-04214, 2:23-cv-04242 (State Attorney General Track)

MANUFACTURER DEFENDANTS' SUPPLEMENTAL BRIEF IN SUPPORT OF MOTIONS TO DISMISS

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INTRODUCTION

In the pre-transfer motion-to-dismiss briefing, the Manufacturers[1] demonstrated that both Illinois's and Montana's (collectively, the "States") claims suffer from a number of fatal defects. Each State asserts a claim—couched in theories of deception and unfairness—under its consumer-protection statute, and a claim for unjust enrichment. Montana also pleads a civil-conspiracy claim. All of these claims fail under settled law:

- The States' deception claims are doomed by the fact that they cannot identify a single instance in which any Manufacturer represented—contrary to federal law—that its list prices reflected PBM rebates or otherwise approximated the net price that it received. And their unfairness claims do not allege anything more than high prices—which is not enough under either State's law. Illinois's statutory claims—for both deception and unfairness—are also barred by a statutory safe harbor for conduct authorized by federal or state law.

- The unjust-enrichment claims fail for several reasons, including because each State concedes that express contracts governed its own insulin purchases, and because the States are unable to identify any way in which the Manufacturers—whose net prices undisputedly remained *flat*—were unjustly enriched.

- Montana's civil-conspiracy claim fails with its underlying claims, and also fails in light of Montana's inability to plausibly allege an unlawful agreement.

- The States' claims are all also untimely. The core dynamic underlying their allegations—the Manufacturers raising insulin list prices to account for PBMs' increasing rebate demands—was well known long before the cut-off for the States' claims (December 2017 for Illinois; September 2019 or 2020 for Montana). That dynamic was disclosed by the Manufacturers themselves, reported in the media, and publicized in congressional hearings and in lawsuits from which both States cribbed their allegations.

The Manufacturers will not repeat those arguments here, and will focus instead on the following additional dispositive points:

[1] Eli Lilly and Company, Novo Nordisk Inc., and Sanofi-Aventis U.S. LLC.

First, the States' deception claims suffer from the same problem that doomed the class plaintiffs' request for injunctive classes: Both depend on the idea that the Manufacturers should have reported list prices that reflect PBM rebates. But as the Court recognized, that premise cannot be reconciled with federal law.

Second, the prior briefing confirms that the States' unfairness claims boil down to nothing more than alleged price inflation. But as the Court held in addressing New Jersey's similar consumer-protection statute, price inflation (without more) is not a cognizable theory of harm. The States have also made clear that they are using their unfairness claims to target supposed price gouging. But neither of their consumer-protection statutes can be stretched in that manner, either.

Third, the States seek to deploy their respective consumer-protection statutes to regulate the Manufacturers' list prices. But the Manufacturers set and report a single list price for sales of their products nationwide, and applying Illinois or Montana law to regulate the prices charged in *other* states would violate the Dormant Commerce Clause.

Finally, the States have tried avoiding applicable statutes of limitations by claiming they could not have been on notice of the congressional hearings and lawsuits on which their claims are predicated. But as demonstrated below, those hearings and lawsuits were well publicized across the country.

ARGUMENT

I. The States' consumer-protection claims fail on the merits.

A. The States' deception claims fail.

The States' consumer-protection claims are premised on the contentions that the Manufacturers' list prices (Wholesale Acquisition Cost, or "WAC") are "false" because they do not reflect the rebates the Manufacturers pay PBMs, and that the Manufacturers should have reported WAC differently. *See* Ill. Compl. ¶ 488, ECF 1-1 (alleging that the Manufacturers "publish[] prices for the at-issue drugs" that are "untethered from the price the Manufacturers were paid for the drugs"); Mont. First Am. Compl. ¶ 513, ECF 40 (alleging that the Manufacturers made "false representations" as to the prices of their insulin products).[2] But federal law *requires* pharmaceutical manufacturers to report WACs "not including prompt pay or other discounts, rebates or reductions in price." 42 U.S.C. § 1395w-3a(c)(6)(B). Indeed, this Court has already said it "does not see" how it could require the Manufacturers to report WACs in some other manner "without causing Defendants to violate federal law." *In re Insulin Pricing Litig.*, 2024 WL 416500, at *28 (D.N.J. Feb. 5, 2024) (Martinotti, J.). For good reason, as any price-reporting obligations under state law that conflict with the definition of WAC under federal law are preempted. *See Farina v. Nokia Inc.*, 625 F.3d 97, 115 (3d Cir. 2010) ("Preemption can apply to all forms of state law, including civil actions based on state law.").

[2] ECF citations are to the pre-MDL dockets: for Illinois filings, *Illinois ex rel. Raoul v. Eli Lilly & Co., et. al.*, No. 1-23-cv-170 (N.D. Ill.); for Montana filings, *Montana ex rel. Knudsen v. Eli Lilly & Co., et. al.*, No. 6-22-cv-87 (D. Mont.).

Under the Constitution's Supremacy Clause, "state law is naturally preempted to the extent of any conflict with a federal statute." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Impossibility preemption applies "when 'compliance with both federal and state regulations is a physical impossibility.'" *In re Fosamax Prod. Liab. Litig.*, 751 F.3d 150, 159 (3d Cir. 2014) (citation omitted). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011).

Under federal law, the Manufacturers report a single WAC for each product they sell. The federal Medicare Act, which defines WAC, contemplates using it to calculate certain Medicare payments. *See* 42 U.S.C. § 1395w-3a(c)(6)(B) (WAC definition); *id.* § 1395w-3a(c)(4) (payment methodology calculated based on WAC); *id.* § 1395w-3a(f) (reporting obligations, including WAC). This statutory scheme assumes that, at any given time, each drug has a single list price. *See* Medicare & Medicaid Programs, Regulation to Require Drug Pricing Transparency, 84 Fed. Reg. 20,732, 20,739 (May 10, 2019) (WAC is "a single, manufacturer-published price" and a "generalizable list price"). And it is impossible to report a WAC that *excludes* rebates and other discounts—in compliance with federal law—while also reporting one *net of* rebates and discounts.

Courts across the nation have found preemption where plaintiffs sought to use state law to govern prices in federally regulated industries. *See, e.g.*, *Pub. Util. Dist. No. 1 of Grays Harbor Cnty. Wash. v. IDACORP Inc.*, 379 F.3d 641, 650 (9th Cir. 2004) (finding state-law claim "asking the court to set a fair price" for electricity was preempted by

federal regulation of electricity rates); *Pharm. Rsch. & Mfrs. of Am. v. D.C.*, 406 F. Supp. 2d 56, 65-67 (D.D.C. 2005) (finding local law prohibiting "excessive" prices for patented pharmaceuticals preempted by federal patent law). In a similar vein, the Supreme Court has recognized that federal law prescribes the manner in which manufacturers must label approved drugs, and that state laws that would require *different* labels are preempted. *See Mensing*, 564 U.S. at 618-19 (state claim preempted because generic manufacturer could not unilaterally change label); *Fosamax*, 751 F.3d at 163-65 (same).

Here, federal law does not permit the Manufacturers to unilaterally redefine WAC. To the contrary, the Medicare Act specifically defines WAC, and provides no mechanism for manufacturers to seek an alternate definition or exemption. Thus, as in *Mensing*, the only way that the Manufacturers could comply with the state-law obligations that the States seek to impose would require them to violate federal law. *Insulin Pricing*, 2024 WL 416500, at *28. That result is untenable.

B. The States' unfairness claims fail.

Without any theory of deception, the States are left to assert that the Manufacturers' list prices are "unfair." This claim is similarly unavailing.

1. The States' price-inflation theory is not cognizable.

The States' unfairness claims boil down to a theory of price inflation. *See* Ill. Compl. ¶ 488 (alleging that the Manufacturers' prices are "artificially inflated"); Mont. First Am. Compl. ¶ 513 (same). But as this Court recently recognized, the Third Circuit has held that a "price inflation theory" is not a "cognizable theory of damages" for

consumer-protection claims under New Jersey or Delaware law. *Insulin Pricing*, 2024 WL 416500, at *37–38; *see also Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 312 (3d Cir. 2016) ("[T]he ascertainable-loss and causal-relationship elements of the NJCFA and the DCFA are not met … [under a] price-inflation theory …."). The theory is equally infirm under other state consumer-protection laws.[3]

In *Harnish*, the Third Circuit explained that "state courts … have emphasized that recognizing 'price inflation' as a 'cause' of 'ascertainable loss' is essentially the same as extending the fraud-on-the-market presumption to all consumer-fraud cases." *Insulin Pricing*, 2024 WL 416500, at *38 (quoting *Harnish*, 833 F.3d at 312-13). And "state courts have refused to recognize either [a fraud-on-the-market or a 'price inflation'] theory outside the federal securities fraud context." *Id.* (quoting *Harnish*, 833 F.3d at 312-13).

This refusal dooms the States' unfairness claims. Montana's statute, like the New Jersey and Delaware laws, requires an "ascertainable loss." Mont. Code § 30-14-133. Illinois's statute similarly requires "actual damage." 815 Ill. Comp. Stat. 505/10a(a). Courts have repeatedly held—as this Court held in *Insulin Pricing*—that those requirements cannot be satisfied with a price-inflation theory. *See*, *e.g.*, *Siegel v. Shell Oil Co.*, 612 F.3d

[3] The States have gone well beyond the consumer plaintiffs by seeking liability for alleged inflation of the prices of novel glucagon-like peptide receptor agonists ("GLP-1s"). They plead no facts to support liability as to GLP-1s, and these claims are preempted by federal patent law. The Manufacturers are currently seeking to leave to move for partial judgment on the pleadings with respect to Mississippi's materially identical allegations as to GLP-1s. MDL ECF 131. If the States' claims were to survive the instant motions, the Manufacturers intend to seek similar relief as to any GLP-1-related claims.

932, 935 (7th Cir. 2010) (holding that "charging an unconscionably high price generally is insufficient to establish a claim for unfairness" under Illinois's consumer-protection law); *Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1336 (S.D. Fla. 2007) (holding that "price inflation" damages are "too speculative" to state a claim under state consumer-fraud statute); *Washington Cnty. Bd. of Educ. v. Mallinckrodt ARD, Inc.*, 431 F. Supp. 3d 698, 712-13 (D. Md. 2020) (holding that "high prices do not in and of themselves constitute false representations," and that allegedly "'inflated' AWPs [could] not serve as the basis of an MCPA claim"). For the same reasons, the States' unfairness claims fail.

2. The States' price-gouging theory is not cognizable.

The unfairness claims fail for a second reason: Both Illinois and Montana have made clear that they seek to hold the Manufacturers liable for what they view as price gouging—but their consumer-protection statutes do not cover alleged price gouging.

Illinois predicates its unfairness claim on the notion that the Manufacturers "price gouge those who have no choice but to pay the price or suffer." Illinois's Opp. to Mfrs.' MTD at 12, ECF 86. And Montana has characterized its consumer-protection statute as a "price gouging statute" for "everything else" (in contrast to another state's actual price-gouging statute for "natural disasters"). Mont. Hearing Tr. at 33, ECF 159. More generally, the basic premise of each State's claim is that their consumer-protection laws should be extended so far as to prohibit supposedly "outrageous price increases" for "life-sustaining drugs" (Ill. Compl. ¶¶ 27–28; Mont. First Am. Compl. ¶¶ 27–28)), and to apply this expansive interpretation to conduct going back a decade.

Neither statute, however, can be retrofitted to function as a price-gouging law. Each law generically prohibits "unfair or deceptive acts or practices." 815 Ill. Comp. Stat. 505/2; Mont. Code § 30-14-103. There is nothing in either statute that would purport to turn that general prohibition into a basis for determining when prices increase to a point at which they somehow become unlawful.

Reinforcing this conclusion, both States' consumer-protection statutes—like those in many other states—are modeled on the Federal Trade Commission Act of 1914 (15 U.S.C. § 45), and are required to be construed consistently with that law. 815 Ill. Comp. Stat. 505/2; Mont. Code § 30-14-104(1). "[T]he [FTC] Act has never been applied to combat price gouging." C. Carpenito et al., *The Federal Response to Hoarding & Price Gouging During the COVID-19 Pandemic*, 30 Am. Bar Ass'n, Pub. Law., No. 2 (Summer 2022). Indeed, "no federal law"—including the FTC Act—"specifically addresses price gouging." A. Vann, Cong. Research Serv., R47072, *Gasoline Price Increases: Federal & State Authority to Limit "Price Gouging"* (Apr. 19, 2022); *see also Gutierrez v. Bean*, 2006 WL 4117064, at *3 (D.N.M. Dec. 13, 2006) ("The Court has been unable to find any evidence of a claim for price … 'gouging' under federal law."). Even the FTC itself has conceded that "[t]here is no U.S. law against price gouging." *FTC v. Lundbeck, Inc.*, 2010 WL 3810015, at *4 n.3 (D. Minn. Aug. 31, 2010), *aff'd*, 650 F.3d 1236 (8th Cir. 2011). This explains why courts routinely reject attempts to police allegedly excessive prices under general consumer-protection laws that track the FTC Act's standards. *Supra* at 6–7; *Sullivan v. Lab. Corp. of Am. Holdings*, 2018 WL 1586471, at *4 (M.D.N.C. Mar. 28,

2018) (contrasting North Carolina's consumer-protection law, which does not contemplate a claim based on "excessive price alone," with its price-gouging law); *Scavio v. Smart Corp.*, 2001 WL 631326, at *3-5 (N.D. Ohio Apr. 26, 2001) (rejecting view that "price gouging" is an "unfair or deceptive practice" under Ohio's consumer-protection law).

By contrast, many *states* have enacted laws that specifically address price-gouging, using targeted, forward-looking rules. Just last year Illinois, for example, enacted a new price-gouging statute that restricts price increases for off-patent and generic prescription drugs. 410 Ill. Comp. Stat. § 725/1, *et seq.* That law, which has no retroactive application, provides a clear mathematical definition of "price gouging," based on a product's WAC and the amount by which it increased. 410 Ill. Comp. Stat. § 725/5. The law also requires a specific showing that the increase "is otherwise excessive and unduly burdens consumers," based on considerations enumerated in the statute. *Id.* The passage of this new statute shows both that the Illinois legislature knows how to proscribe "inflated" prices, and that the Illinois consumer-protection statute—which merely prohibits "unfair" trade practices—does *not* capture this conduct.[4]

Montana, for its part, does not have a pharmaceutical price-gouging statute—because its legislature chose *not* to enact one. In 2021, the legislature considered—and

[4] Illinois also recently considered—and *rejected*—a price-gouging bill that would have amended the Illinois Consumer Fraud Act to prohibit "unconscionably high" prices for, among other things, "medical supplies," during "declared" "disaster[s]." HB5795, 101st Gen. Assemb. (Ill. 2020). This only further confirms that the Consumer Fraud Act does not create a cause of action for allegedly "egregious[]" prices. Ill Compl. ¶ 490.

rejected—a draft bill like Illinois's, entitled the "Montana Prohibition on Prescription Drug Price Gouging Act." LC0008, 2021 Leg., 67th Sess. (Mont. 2021) (Ex. A). This explains why Montana is left analogizing to *actual* price-gouging statutes in other states.

Allowing the States to extend their consumer-protection statutes to alleged price gouging would also raise serious due-process questions of notice and vagueness. "A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). This principle forbids holding a defendant liable based on an "unforeseeabl[e] and retroactive[] expan[sion]" of some statute "by judicial construction." *Bouie v. City of Columbia*, 378 U.S. 347, 352 (1964). But interpreting general consumer-protection statutes to establish pricing regulations akin to the rules set by *actual* price-gouging statutes, and to forbid WACs above some undefined threshold, would effectuate just such an "unforeseeabl[e] and retroactive[]" expansion. *Id.*

C. The States' claims violate the Dormant Commerce Clause.

The States' claims—for deception *and* unfairness—also fail because crediting them would violate the Dormant Commerce Clause's prohibition of "state laws that unduly restrict interstate commerce." *Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 139 S.Ct. 2449, 2459 (2019). The States cannot use their consumer-protection laws to regulate or control the *nationwide* list prices that manufacturers set, even for transactions having no relationship whatsoever to the relevant state.

First, the Dormant Commerce Clause bars allowing a state law to "*directly* regulate[] out-of-state transactions by those with *no* connection to the State." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 376 n.1 (2023); *see also Edgar v. MITE Corp.*, 457 U.S. 624, 641–43 (1982) (plurality op.) (declining to enforce an Illinois securities law that "directly regulate[d] transactions which [took] place … wholly outside the State" and involved individuals "having no connection with Illinois").

That, however, is exactly what the States propose. As the Court has already recognized, federal law requires—and the Manufacturers thus set—a single WAC for each of their products. *See* 42 U.S.C. § 1395w-3a(c)(6)(B); *supra* at 4. There are no state-specific WACs. Nevertheless, the States contend that the Manufacturers' nationwide list prices violate their respective consumer-protection statutes, and seek to use those state laws to determine the prices the Manufacturers can set for their insulin products—necessarily regulating prices for *all* sales of those products to wholesalers, nationwide.

The Dormant Commerce Clause forbids this outcome. *Pork Producers*, 598 U.S. at 376 n.1. Indeed, multiple courts have struck down state laws that prohibited—as the States seek to do here—"unconscionable" drug prices. The Fourth Circuit invalidated a Maryland law that "instructs prescription drug manufacturers that they are prohibited from charging an 'unconscionable' price in the initial sale of a drug, which occurs outside Maryland's borders." *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 672–73 (4th Cir. 2018). Because the law had the effect of "specify[ing] the price at which goods may be sold beyond Maryland's borders," it violated the Dormant Commerce Clause. *Id.* at

673. And a Minnesota district court reached the same conclusion last year, as to a similar state law that would regulate pharmaceutical list prices in "out-of-state drug transactions between parties that have no connection whatsoever to Minnesota." *Ass'n for Accessible Meds. v. Ellison*, 2023 WL 8374586, at *4 (D. Minn. Dec. 4, 2023). The court held that the law's "regulation of transactions with such an attenuated connection to Minnesota clearly violates the dormant Commerce Clause." *Id.* Similarly here, the States cannot use their consumer-protection laws to regulate the Manufacturers' nationwide WACs.

Second, even if the States' claims did *not* directly regulate out-of-state conduct, they would still violate the Dormant Commerce Clause because "the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).[5] The burden that the States seek to impose is overwhelming: determining the very prices the Manufacturers can set for their products nationwide. Allowing this result would fundamentally undermine the federal statutory framework governing drug pricing, not only by "requir[ing] manufacturers and wholesale distributors to do more than alter their distribution channels," but by "superseding market forces that dictate the price of a good." *Frosh*, 887 F.3d at 673. Indeed, Montana has admitted as much. *See* Mont. Hearing Tr. at 42 ("We would have to overhaul this entire system for the price to have any market force applied to it that would

[5] The Supreme Court recently reaffirmed that *Pike* does not require purposeful discrimination against out-of-state entities or commerce. *Pork Producers*, 598 U.S. at 379–80 (plurality op.); *id.* at 391–92 (Sotomayor and Kagan, JJ. concurring in part); *id.* at 395–96 (Roberts, C.J., and Alito, Kavanaugh, Jackson, JJ., concurring in part).

cause it to go down."). And these burdens—which would fall overwhelmingly on interstate commerce—vastly exceed any local benefits that either State would realize.

This MDL underscores the impossible bind the Manufacturers would be in if state consumer-protection laws could be used to regulate their list prices. Collectively, this MDL includes claims against the Manufacturers under nearly every state's consumer-protection laws. And the plaintiffs seek to have this Court determine that the Manufacturers' WACs at some point became unlawful under each of those many state laws. Even if the Court *could* make that judgment as to any particular law—under standards that plainly vary from state to state—the result would be a patchwork of rules. *See, e.g.*, *Frosh*, 887 F.3d at 673 ("[A]n analogous restriction imposed by a state other than Maryland has the potential to subject prescription drug manufacturers to conflicting state requirements."). The Dormant Commerce Clause prevents precisely such "inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State." *Healy v. Beer Inst.*, 491 U.S. 324, 336–37 (1989).

II. All of the States' claims are time-barred.

As the Manufacturers' original briefing showed, the States were on notice of the facts underlying their claims long before they sued. The relationship between rebates and insulin prices has long been widely known. Indeed, both States advance the exact theory of liability asserted in the putative consumer class action filed more than five years before they sued. This issue has also for years been the subject of extensive legislative scrutiny, both in the U.S. Congress and in the States' respective legislatures.

The States have suggested they were not on notice of this conduct until years later. Montana's MTD Opp. at 36–38, ECF 112; Illinois's MTD Opp. at 27–29, ECF 86. But the lawsuits from which they cribbed their allegations, and the congressional hearings specifically addressing insulin pricing, received significant coverage in major nationwide media sources. *See, e.g.*, K. Thomas, *Drug Makers Accused of Fixing Prices on Insulin*, N.Y. TIMES (Jan. 30, 2017) (Ex. B); C. Johnson, *Diabetes Patients Sue Insulin Makers for 'Pricing Fraud'*, WASH. POST (Jan. 30, 2017) (Ex. C); *Lawsuit Accuses Drug Makers of Conspiring to Hike Insulin Prices*, CBS NEWS (Feb. 22, 2017) (Ex. D); N. Raymond, *Minnesota Accuses Insulin Makers of Deceptive Drug Pricing*, REUTERS (Oct. 16, 2018) (Ex. E); R. Pear, *Drug Makers Try to Justify Prescription Prices to Senators at Hearing*, N.Y. TIMES (Feb. 26, 2019) (Ex. F); A. Kodjak, *Pharmaceutical Company CEOs Face Grilling In Senate Over High Drug Prices*, NPR (Feb. 26, 2019) (Ex. G).[6] This coverage—in addition to the Manufacturers' own public representations and disclosures, legislative action in each of the States, and additional news reports—only further underscores that the information underlying the States' claims was in the public sphere long before either State sued. Mfrs.' Mont. MTD at 14–19; Mfrs.' Ill. MTD at 25–28.

CONCLUSION

For the reasons set forth above and in the Manufacturers' prior briefing, the Court should dismiss all of Illinois's and Montana's claims against the Manufacturers.

[6] Under Illinois and Montana law, the Court can take judicial notice of these news reports. Mfrs.' Mont. MTD at 17 n.4, ECF 85; Mfrs.' Ill. MTD at 26 n.8, ECF 60.

Dated: April 24, 2024

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Exhibit A

Unofficial Draft Copy

_____ BILL NO. _____

INTRODUCED BY _____
(Primary Sponsor)

A BILL FOR AN ACT ENTITLED: “AN ACT PREVENTING EXCESSIVE PRICES FOR PRESCRIPTION DRUGS; ESTABLISHING REMEDIES FOR EXCESSIVE PRICE INCREASES; PROHIBITING WITHDRAWAL OF PRESCRIPTION DRUGS FROM MONTANA IN CERTAIN INSTANCES; PROVIDING PENALTIES; PROVIDING DEFINITIONS; PROVIDING RULEMAKING AUTHORITY; AND PROVIDING A DELAYED EFFECTIVE DATE.”

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Short title.** [Sections 1 through 7] may be cited as the "Montana Prohibition on Prescription Drug Price Gouging Act".

NEW SECTION. **Section 2. Purpose.** It is the purpose of [sections 1 through 7] to protect the health, safety, and economic well-being of the state and the residents of this state by guarding them from the negative and harmful impact of excessive prices for prescription drugs.

NEW SECTION. **Section 3. Definitions.** As used in [section 1 through 7], the following definitions apply:

(1) "Applicable manufacturer" means a manufacturer, as defined in 37-7-602, of prescription drugs that are sold in the state whether directly or through a distributor, sufficient to confer either general or specific jurisdiction over the manufacturer by a court of this state.

(2) “Consumer price index” means:

(a) the consumer price index, United States city average, for all items, for all urban consumers, as published by the bureau of labor statistics of the United States department of labor, or its successor; or

(b) if the index is discontinued, an equivalent reported by a federal authority. If no such index is reported, the term means a comparable index chosen by the bureau of labor statistics.

(3) "Distributor" means a wholesale distributor as defined in 37-7-602 that procures prescription drugs from an applicable manufacturer for sale or distribution in the state and/or that distributes or sells the prescription drugs in the state, sufficient to confer either general or specific jurisdiction over the distributor by a court of this state.

(4) "Prescription drug" has the meaning provided in 33-22-170.

(5) "Wholesale acquisition cost" has the meaning provided in 42 U.S.C. 1395w-3a.

NEW SECTION. **Section 4. Excessive price increases prohibited.** (1) It is a violation of [sections 1 through 7] for an applicable manufacturer or a distributor to impose an excessive price increase, whether directly or through a distributor, on the sale of any prescription drug sold, dispensed, or delivered in the state to any consumer in the state.

(2) A price increase is excessive for purposes of [sections 1 through 7] when the price increase, after being adjusted for inflation using the consumer price index, exceeds:

(a) 10% of the wholesale acquisition cost during the immediately preceding calendar year; or

(b) 30% of the wholesale acquisition cost during the immediately preceding 3 calendar years.

NEW SECTION. **Section 5. Enforcement.** (1) An applicable manufacturer or a distributor shall notify the state attorney general of any price increase of a prescription drug that is in violation or in apparent violation of [section 4].

(2) Within 30 days of receipt of the notice, the attorney general shall provide the applicable manufacturer or the distributor with notice of receipt by serving the notice on the applicable manufacturer's or the distributor's registered agent. The notice must:

(a) advise the applicable manufacturer or the distributor that the attorney general has received notice pursuant to subsection (1);

(b) notify the applicable manufacturer or the distributor of the terms set forth in subsections (4) through (6) ; and

(c) require the applicable manufacturer or the distributor to submit a response pursuant to subsection (4).

(3) Within 60 days of receipt of notice under subsection (2), the applicable manufacturer or the distributor of the prescription drug shall submit a statement to the attorney general:

(a) itemizing the components of the cost of producing the prescription drug;

(b) identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the prescription drug during the preceding year; and

(c) providing any other information that the applicable manufacturer or the distributor believes to be pertinent to a determination of whether a violation of [section 4] has occurred.

(4) The attorney general may require an applicable manufacturer or a distributor to produce any records or documents that may be relevant to a determination of whether a violation has occurred.

(5) On petition of the attorney general, a court of competent jurisdiction may issue an order:

(a) compelling the applicable manufacturer or the distributor:

(i) to provide a statement required under subsection (3); or

(ii) to produce records or documents requested by the attorney general under subsection (4) that may be relevant to a determination of whether a violation of [section 4] has occurred;

(b) restraining or enjoining a violation of this act,

(c) requiring prices be restored to levels that comply with [section 4];

(d) requiring the applicable manufacturer or the distributor to provide an accounting to the attorney general of all revenues generated in violation of [section 4];

(e) restoring to any consumer, including any third-party payor, any money acquired as a result of a price increase that violates or has been adjudged to have violated [section 4];

(f) requiring that all revenues generated in violation of [section 4] be remitted to the state general fund to be used for efforts designed to reduce the cost to state residents of acquiring prescription drugs, if the applicable manufacturer or the distributor is unable to provide the restitution required in subsection (4)(e);

(g) imposing a civil penalty of up to $10,000 a day for each violation of this act; and

(h) providing for any other appropriate relief, including costs of suit reasonably incurred by the attorney general in bringing action against the applicable manufacturer or the distributor found in violation of [section 4] above.

(6) For the purposes of subsection (5)(g), each individual transaction in violation of [section 4] is a

separate violation of [this act].

NEW SECTION. **Section 6. Prohibition on withdrawal of prescription drugs for sale.** (1) It is a violation of [sections 1 through 7] for an applicable manufacturer or a distributor to directly or through a distributor withdraw a prescription drug from sale or distribution in the state for the purpose of avoiding the pricing prohibitions of [section 4].

(2) If the attorney general believes a drug has been withdrawn from sale or distribution in the state in violation of this section, the attorney general shall notify the applicable manufacturer or the distributor that:

(a) the attorney general intends to assess the penalty provided for in this section; and

(b) the applicable manufacturer or the distributor may request a hearing under the contested case procedures of Title 2, chapter 4, to offset the imposition of the penalty.

(3) The attorney general shall assess a penalty of $1 million on an applicable manufacturer or a distributor that the attorney general determines has withdrawn a prescription drug from sale or distribution in the state in violation of this section.

NEW SECTION. **Section 7. Rulemaking authority.** The attorney general may adopt rules necessary to implement the provisions of [sections 1 through 7].

NEW SECTION. **Section 8. Codification instruction.** [Sections 1 through 7] are intended to be codified as an integral part of Title 30, chapter 14, and the provisions of Title 30, chapter 14, apply to [sections 1 through 7].

NEW SECTION. **Section 9. Effective date.** [This act] is effective January 1, 2022.

- END -

Exhibit B

The New York Times https://www.nytimes.com/2017/01/30/health/drugmakers-lawsuit-insulin-drugs.html

Drug Makers Accused of Fixing Prices on Insulin

By Katie Thomas

Jan. 30, 2017

A lawsuit filed Monday accused three makers of insulin of conspiring to drive up the prices of their lifesaving drugs, harming patients who were being asked to pay for a growing share of their drug bills.

The price of insulin has skyrocketed in recent years, with the three manufacturers — Sanofi, Novo Nordisk and Eli Lilly — raising the list prices of their products in near lock step, prompting outcry from patient groups and doctors who have pointed out that the rising prices appear to have little to do with increased production costs.

The lawsuit, filed in federal court in Massachusetts, accuses the companies of exploiting the country's opaque drug-pricing system in a way that benefits themselves and the intermediaries known as pharmacy benefit managers. It cites several examples of patients with diabetes who, unable to afford their insulin treatments, which can cost up to $900 a month, have resorted to injecting themselves with expired insulin or starving themselves to control their blood sugar. Some patients, the lawsuit said, intentionally allowed themselves to slip into diabetic ketoacidosis — a blood syndrome that can be fatal — to get insulin from hospital emergency rooms.

A recent study in The Journal of the American Medical Association found that the price of insulin nearly tripled from 2002 to 2013.

“People who have to pay out of pocket for insulin are paying enormous prices when they shouldn’t be,” said Steve Berman, a lawyer whose firm filed the suit on behalf of patients and is seeking to have it certified as a class action.

In a statement, Sanofi said, “We strongly believe these allegations have no merit, and will defend against these claims.” Lilly said it had followed all laws, adding, “We adhere to the highest ethical standards.”

A spokesman for Novo Nordisk said the company disagreed with the allegations in the suit and would defend itself. “At Novo Nordisk,” the company’s statement said, “we have a longstanding commitment to supporting patients’ access to our medicines.”

The rising costs of drugs has led to several hearings in Congress and has drawn the attention of President Trump, who this month pledged to address the issue and said the industry was “getting away with murder.”

Boxes of Humalog, an insulin made by Eli Lilly. Lilly, Sanofi and Novo Nordisk have been accused in a lawsuit of exploiting the country’s opaque drug-pricing system in a

way that benefits themselves and the intermediaries known as pharmacy benefit managers. George Frey/Bloomberg

In December, attorneys general in 20 states accused several generic drug makers, including two of the biggest — Teva Pharmaceuticals and Mylan — of engaging in a price-fixing scheme in which executives coordinated at informal gatherings and through phone calls and text messages. Federal investigators are also said to be looking at the issue of drug prices, and several companies, including Valeant Pharmaceuticals International, have said they have received subpoenas.

Several companies have recently tried to head off criticism by taking actions to address rising prices. In December, Lilly said it would offer a 40 percent discount off the list price of its insulin product, Humalog, for patients who are forced to pay full price. And Novo Nordisk, which makes Novolog, has pledged to limit price increases in the American market to less than 10 percent in a year.

The lawsuit filed Monday claimed that the three companies intentionally raised the list prices on their drugs to gain favorable treatment from pharmacy benefit managers, who work with health insurers and drug makers and help decide how a drug will be covered on a list of approved drugs.

Insurers do not pay the list prices that the drug makers set. Instead, the pharmacy benefit managers negotiate a rebate that is returned to them. The benefit managers, in turn, take a slice of that rebate for themselves, although the amount of the rebate, and the amount they keep, is not made public.

As a result, the drug manufacturers end up setting two prices for their drugs — the higher list price and the lower, secret, “real” price that insurers pay. The lawsuit claims that rather than competing with one another to offer a lower, “real” price to the insurers, the drug makers are vying to offer the best payment to the pharmacy benefit manager, which is why they have been raising the list price.

When the list price goes up, many patients see their out-of-pocket costs rise, even if they have health insurance. That’s because plans increasingly carry high deductibles, which require patients to pay for their drug costs themselves until

they hit a certain limit, as well as to pay a percentage of the list price even after their deductible is met.

While Mr. Berman accused the benefit managers of being complicit, he said the lawsuit focused on the drug makers because “they are playing the game, and they are the ones who publish the list price.”

Michael Carrier, an antitrust professor at Rutgers Law School, described the filing of the lawsuit as “big news” and said it was interesting because it turned its attention to the inner workings of the pharmacy benefit managers, which until now “have floated under the radar of sustained drug pricing scrutiny.”

Brian Henry, a spokesman for Express Scripts, the nation’s largest pharmacy benefit manager, declined to comment on the lawsuit, but said, “Rebates don’t raise drug prices, drug makers raise drug prices.”

A version of this article appears in print on , Section A, Page 22 of the New York edition with the headline: Three Drug Makers Are Accused of Conspiring to Raise Insulin Prices

Exhibit C

The Washington Post
Democracy Dies in Darkness

ECONOMIC POLICY

Diabetes patients sue insulin makers for 'pricing fraud'

By Carolyn Y. Johnson

January 30, 2017 at 6:05 p.m. EST

A group of diabetes patients filed a lawsuit Monday against three drug companies for systematically increasing the list prices of insulin for years in an alleged fraudulent-pricing scheme that saddled patients with "crushing out-of-pocket expenses," according to the filing.

The insulin market is dominated by an oligopoly of companies that sell many billions of dollars worth of insulin each year — and have steadily raised the list prices of their drugs. A version of insulin called Humalog launched two decades ago with a sticker price of $21 a vial and has increased to $255 a vial.

Meanwhile, competition has appeared to work in a perverse way, with list prices of competing insulins often rising in concert. Last year, Sen. Bernie Sanders (I-Vt.) and Rep. Elijah E. Cummings (D-Md.) asked for a federal investigation into "possible collusion" on insulin prices.

The lawsuit, filed by 11 patients in U.S. District Court in Massachusetts, focuses on a common practice in the pharmaceutical industry: Drug companies compete for insurers' business by offering secret rebates on their drugs. Companies that negotiate drug prices for insurers, called pharmacy benefit managers, can place drugs on tiers that determine how much consumers pay for them — decisions that may be influenced by the size of the discount granted by the drug companies.

The lawsuit claims that drug companies have been increasing the list price of insulin in order to expand their discounts without lowering the overall price tag. The people stuck paying the balance: patients, particularly those without insurance or with high-deductible plans. The lawsuit alleges those actions violate the Racketeer Influenced and Corrupt Organizations Act and state consumer protection laws.

"I think that publishing a price that you know is artificially inflated and is not a real price — other than to one group of people — is a fraud," said Steve Berman, a partner in the with Hagens Berman law firm who represents the plaintiffs.

The lawsuit describes a patient who may need to have her foot amputated because she cannot afford her insulin. Others, it says, have intentionally allowed themselves to develop a potentially life-threatening syndrome so that they can be admitted to a hospital and obtain free insulin samples.

“This scheme directly and foreseeably causes consumers to overpay for these life-saving medications,” the lawsuit states.

Insulin companies acknowledge that list prices have risen but argue that net prices — the amount drug companies are paid after rebates — haven't budged.

Eli Lilly “conducts business in a manner that ensures compliance with all applicable laws, and we adhere to the highest ethical standards,” spokesman Greg Kueterman said in an email, declining to comment further.

A spokeswoman for Sanofi said that the company believes the allegations have no merit and will defend against them.

Novo Nordisk spokesman Ken Inchausti said in an email: “We are aware of the complaint and its characterization of the pharmaceutical supply chain. We disagree with the allegations made against the company and are prepared to vigorously defend the company in this matter.”

The Pharmaceutical Care Management Association, a trade group that represents pharmacy benefit managers, said it is reviewing the lawsuit and pointed out that its companies are not defendants. But in a statement, the association said the lawsuit “inexplicably attacks prescription drug rebates, long used to reduce costs in public programs like Medicaid and in the commercial market.”

Rising drug list prices have become a major issue for the biopharmaceutical industry as various pricing controversies triggered by list-price hikes have flared into congressional hearings and prompted other scrutiny over the past year and a half. Although drugmakers grant discounts off the list prices to pharmacy benefit companies, those may not always be passed through directly to consumers.

For example, people with high-deductible plans or co-insurance requiring them to pay a percentage of the drug cost can be directly affected by rising list prices. As more consumers are using health insurance that includes high deductibles, more patients are being exposed to the list price of a drug. In addition, insulin is a drug people take for a lifetime, so any gaps in health insurance or issues such as losing or breaking a vial of insulin could expose them to the list price of their medicine.

The lawsuit says pharmacy benefit managers that negotiate on drug prices for insurers play a role in the alleged scheme by telling the public the rebates were saving patients and insurers money, even when they know rebates aren't lowering the real price of the insulin.

Brian Henry, a spokesman for Express Scripts, one of the largest pharmacy benefit managers, declined to comment on the lawsuit, but he said in an email, “Rebates don’t raise drug prices. Drugmakers raise drug prices.”

Erin Britt, a spokeswoman for CVS Health said that the company passes more than 90 percent of its rebates back to customers.

Exhibit D

CBS MORNINGS

Lawsuit accuses drug makers of conspiring to hike insulin prices

Updated on: February 22, 2017 / 7:48 AM EST / CBS News

More than 29 million Americans live with diabetes, and for some six million of them, insulin is a life or death medication.

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Between 2002 and 2013, the price of insulin more than tripled, to more than $700 per patient. A federal lawsuit accuses the three insulin manufacturers of conspiring to raise their prices. The drug makers deny the allegations.

Those high prices, combined with rising insurance deductibles, mean many people who rely on insulin are feeling sticker shock. Even doctors say without a way to pay, some patients are left facing impossible choices, reports CBS News correspondent Anna Werner.

- **Contact us about this issue or other consumer problems you think we should look into at consumer@cbsnews.com.**

A cell phone video shows Dr. Claresa Levetan talking to her patient Shawna Thompson back in the hospital because she couldn't pay for her insulin.

"One vial of insulin costs how much for you?" Levetan asked.

"One hundred and seventy-eight dollars," Thompson responded.

It was the fourth time in just over a year that Thompson had to be treated for a life-threatening diabetic coma.

"Patients come in and say I can't afford to take it, so I'm not," Levetan said. She said it's common for her now to hand out free drug company samples of insulin, just so patients can stay on their lifesaving medication.

"Patients are begging for samples because they can't afford the insulin," Levetan said.

"Not asking, you're saying, begging," Werner said..

"Begging," Levetan said.

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Like 74-year-old Kathleen Washington. Some months, her insulin runs over $300 a month - more than she can afford.

"I must pay my mortgage," Washington said.

If it's a choice between the mortgage and the insulin, "It's going to be the mortgage," she said.

Investment research firm SSR Health analyzed insulin list prices from 2012 to 2016 for the three companies that manufacture it, and found prices went up between 99 and 120 percent.

In a separate analysis, SSR Health's Richard Evans also found a striking pattern: the prices of two prime insulin drugs rose in lockstep - mirroring each other - 12 times between 2008 and 2014.

"The two companies took price increases within days of one another, and the price increases were similar - even identical - to the percentage point," Evans said.

"If you raise your price, and I raise my price to the same level, what am I saying to you as a company?" Werner asked.

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"Let's keep going, or, I'm not going to fight you," Evans said.

Vermont Sen. Bernie Sanders is calling for a federal investigation, alleging collusion among the three drug companies: Eli Lilly, Novo Nordisk and Sanofi.

"Just coincidentally it happens that the three major suppliers of insulin seem to be raising their prices at the same exact time, at the same level. So I think you have to be very naïve not to believe there is collusion," Sanders said.

The companies deny they've broken any laws. Sanofi told CBS News there is "strong competition" on price. Eli Lilly said it is "aggressively competing on net (or negotiated) price," and Novo Nordisk's president said on the company's website that increasing list prices is designed to offset rebates and price concessions to maintain profitability.

Lori Reilly, with the trade group that represents U.S. pharmaceutical manufacturers, told CBS News, "I don't believe there's been collusion by our companies."

She pointed out although the drug companies list prices are up, the negotiated prices for insulin, what the industry calls "net" prices, have gone up just 2 to 3 percent overall. She said that's because intermediaries called pharmacy benefit managers, or PBMs, negotiate

for rebates from drug companies, take a fee, then pass those lower "net" prices on to

insurance companies and ultimately consumers.

The problem, Evans said, is patients who have high deductibles or little or no insurance don't get those discounted prices.

"So in other words, the people who can least afford these increases are the ones who get hit by them," Werner said.

"Everybody gets hit by them a little bit, but people that can't afford it get hit disproportionately," Evans said.

But Reilly said, "When you look at the evidence, the competitive marketplace is working, and it's working very aggressively to help keep drug cost increases in check."

"I'm listening to that statement and I'm hearing consumers go, 'Are you kidding me?'" Werner said.

"There is an issue for many patients who today face increasing deductibles," Reilly said. "If those patients are coming to the pharmacy counter and they're paying full list price, while their insurance company or pharmacy benefit manager has bought that drug at a 50 or 60 percent discount, that is a problem."

The country's largest pharmacy benefit manager told CBS News drug makers are the ones raising their prices. But experts tell us there's plenty of blame to go around. Meanwhile, all three insulin manufacturers say they've announced new initiatives to make insulin more affordable.

Novo Nordisk responds:

Many Americans struggle to pay for our medicines and we are focused on working collaboratively toward sustainable solutions.

On Massachusetts class action lawsuit:

"We are aware of the complaint and its characterization of the pharmaceutical supply chain. We disagree with the allegations made against the company, and are prepared to vigorously defend the company in this matter. At Novo Nordisk, we have a longstanding

commitment to supporting patients' access to our medicines. Since this is an ongoing

litigation, we can't comment further."

On shadow pricing allegations:

"Under the system that has evolved here in America, the actual price received by a manufacturer is not the list price or the Average Wholesale Price, but rather the net price after very competitive negotiations with a number of middlemen who operate between those of us who make insulin and the patients who use our medicines to control their diabetes."

On Sen. Sanders' collusion allegations:

"Novo Nordisk is committed to developing innovative medicines for patients with diabetes. We set price for these life-saving medicines independently and then negotiate with payers and PBMs to ensure patients have access to them. We stand by our business practices and our efforts to improve the lives of patients with diabetes."

Eli Lilly responds:

"Today's health care system works well for many people, but those enrolled in high-deductible insurance plans and managing chronic conditions face challenges in gaining reasonable access to the treatments they need. Diabetes is one example, and we are committed to doing our part.

"Lilly recently announced an innovative program to provide insulin at a discounted price. Starting January 1, people who pay the highest out-of-pocket prices for insulin, including those who have no insurance or are in the deductible phase of their high-deductible insurance plans, may directly benefit from a 40 percent discount via mobile and web platforms hosted by Blink Health.

"We also intend to work with health plans on innovative approaches so patients can directly benefit from negotiated discounts during the deductible phase."

On Massachusetts class action lawsuit:

"Lilly disagrees with the allegations reported to be in the lawsuit. We conduct business in a manner that ensures compliance with all applicable laws, and we adhere to the highest

ethical standards."

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On shadow pricing allegations:

"We are in strict compliance with all federal regulation and guidelines on all aspects of our business, including drug pricing, and we are committed to providing the best medicines to people with diabetes at the best price available.

"The pharmaceutical industry is very competitive, and just like in other competitive industries, we monitor publicly available data to understand what other companies are doing. Sometimes, that means adjusting our prices, which helps our insulins remain available on formularies for people with diabetes. We make price adjustments after considering multiple factors, including the list prices of other treatments in the market. Importantly, list prices are a starting point, so they are not an adequate measure of competition. Net realized prices - after negotiations on rebates and fees, and other costs are factored in - are the real measurement of competition. We are aggressively competing on net price. For instance, while the list price for Humalog® has gone up, Lilly actually receives a lower average net price now than in 2009."

On Sen. Sanders' collusion allegations:

"Lilly denies the accusation. Lilly conducts business in a manner to ensure compliance with all applicable laws, and we adhere to the highest ethical standards."

Sanofi responds:

"Sanofi fully understands that the price and affordability of our products is important for patients, and we are committed to helping patients get the treatment they are prescribed. We offer patient assistance programs for patients in need and copay programs for qualified patients whose prescriptions are not paid in part or fully by any state or federally funded program.

"Our goal is to help patients remain on their current treatment and not have to change treatments just because of changes in their coverage. To help with this, we have recently introduced a new copay offer for eligible patients to pay no more than $10 per prescription for either Lantus or Toujeo for up to 12 months regardless of insurance coverage.

"The new copay offer helps patients on traditional commercial insurance including those on high-deductible plans as well as those who pay cash. More specifically:

- Patients who pay cash and use the copay card receive $100 off Lantus SoloStar or vial box which is a 27-40% discount, or for Toujeo, they receive $200 off per box which is a 60% discount.
- Patients on high-deductible plans who use the co-pay card or evoucher, which will automatically activate at participating pharmacies when their out of pocket costs are above a certain cost level, pay no more than $10 per prescription."

On Massachusetts class action lawsuit:

"We strongly believe these allegations have no merit, and will defend against these claims. Since this is related to pending litigation, it would be inappropriate to comment further," said Ashleigh Koss, Sanofi Head of Media Relations, North America.

On shadow pricing allegations:

"Sanofi operates with the highest ethical business standards and complies with all laws and regulations that govern our business. There is strong competition in the marketplace that also factors into how we set the prices of our treatments. Sanofi fully understands that the price and affordability of our products is important for patients. We have not increased the list price of Lantus since November 2014. In fact, the net price of Lantus over the cumulative period of the last five years has decreased because of efforts to remain included on formularies at a favorable tier which helps to reduce out of pocket costs to patients. In setting prices for our insulin medications, we work to balance helping patients manage their diabetes today and developing ways to improve care in the future. We also offer assistance programs for patients in need."

On Sen. Sanders' collusion allegations:

"Sanofi operates with the highest ethical business standards and complies with all laws and regulations that govern our business. There is strong competition in the marketplace that also factors into how we set the prices of our treatments. Sanofi fully understands that the price and affordability of our products is important for patients. We have not increased the list price of Lantus since November 2014. In fact, the net price of Lantus

over the cumulative period of the last five years has decreased because of efforts to remain included on formularies at a favorable tier which helps to reduce out of pocket costs to patients. In setting prices for our insulin medications, we work to balance helping patients manage their diabetes today and developing ways to improve care in the future. We also offer assistance programs for patients in need."

Express Scripts (PBM) responds:

"While drug companies have increased the price of insulin, the net costs to payers have been held down. That's because PBMs like us are doing our job in delivering savings to our clients - the employers, health plans and government entities that pay the most for medicines in this country. Rebates are delivered to those entities and they are used to help bring down benefit premiums and also to ensure a robust pharmacy benefit is provided to workers and families. It is the payers' decision on how they want to return those rebates to their members. For example, we can, and do at the direction of our clients, provide point of sale rebates directly to a plan member. Most plans would rather receive the rebates and deploy them as they see fit to lower premiums and enhance the benefit.

The main takeaway is this: Rebates don't raise drug prices, drug makers raise drug prices.

Also, a few other notes about rebates:

- CMS' recent fact sheet noted rebates (as DIR) reduced Part D spending $411 per beneficiary in 2015.
- In 2014, Medicaid spent $42 billion on Rx, but received $20 billion in rebates.
- Without rebates, how will these public programs afford prescription drugs?"

Sen. Bernie Sanders weighs in:

On Facebook: "Americans pay by far the highest prices for prescription drugs in the world. During the campaign Mr. Trump said that he would take on bigPharma and lower the cost of drugs. Today, he met with executives from the pharmaceutical industry – an industry where the top 5 companies made $50 billion in profits in 2015. Funny thing though. He talked about tax breaks for this tremendously profitable industry, but what he did not talk about was his campaign promise to allow Medicare the ability to negotiate prices with the drug companies. It appears Trump has already sold out the American people regarding his

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promise not to cut Social Security, Medicare and Medicaid. Is he going to sell them out again and cave to the drug companies as well?

"Meanwhile, I and colleagues will be introducing legislation to significantly lower prescription drug prices in this country, allowing our people to purchase low-cost prescription drugs from abroad and having Medicare negotiate prices with drug companies. Will Trump support this legislation and lower drug prices? Stay tuned."

On working with the president: "I look forward to working with President Trump on this issue if he is serious about standing up to the pharmaceutical industry and reducing drug prices."

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First published on February 22, 2017 / 6:51 AM EST

Exhibit E

Minnesota accuses insulin makers of deceptive drug pricing

reuters.com/article/idUSKCN1MR03B/

FILE PHOTO: A Novo Nordisk employee controls a machine at an insulin production line in a plant in Kalundborg, Denmark November 4, 2013. REUTERS/Fabian Bimmer/File Photo
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(Reuters) - Minnesota's attorney general on Tuesday filed a lawsuit accusing drug manufacturers Sanofi SA, Novo Nordisk and Eli Lilly and Co of deceptively raising prices for insulin.

In a lawsuit filed in federal court in Trenton, New Jersey, Minnesota Attorney General Lori Swanson took aim at the companies after the list price for some insulin products more than tripled since 2002.

The lawsuit alleged that companies fraudulently set artificially high list price for their products while offering rebates to pharmacy benefit managers (PBMs) in exchange for them covering the drug on behalf of health plans.

PBMs negotiate drug prices for employers and health plans and typically demand hefty discounts off list price from drugmakers in exchange including the medicines on their preferred formularies.

The lawsuit contended that the list prices the drug companies set were so far from those net prices that they did not accurately approximate the true cost of insulin and were deceptive and misleading.

The practice made insulin less affordable for diabetes patients in high deductible health plans, the uninsured and senior citizens covered by the government Medicare healthcare program, the suit contended.

"Many people can’t afford the price hikes but can’t afford to stop taking the medication either," Swanson said in a statement.

Danish drugmaker Novo Nordisk in a statement said it was "committed to ethics and compliance in how we support patients." French drugmaker Sanofi and Indianapolis-based Lilly in separate statements said they believed the case was without merit.

The lawsuit comes amid continued concerns about rising U.S. drug costs, particularly for insulin, a hormone needed by many people with diabetes to control blood sugar levels.

Swanson's lawsuit marked the first by a state to target pricing practices of insulin manufacturers. The case was filed in New Jersey, where a similar proposed class action lawsuit is pending.

Two other states, Washington and New Mexico, have been conducting similar investigations, according to Novo Nordisk.

Novo's insulin products include Levemir, whose cost according to Swanson has risen from $120.64 per vial in 2012 to $293.75 in 2018. There have been similar price hikes for Lilly's HumaLog and Sanofi's Lantus, the lawsuit said.

The lawsuit seeks an injunction preventing the companies from disseminating misleading list prices for insulin products. It also seeks damages for Minnesota residents who paid out-of-pocket for their insulin.

But it comes a day after the U.S. government said it would propose requiring drugmakers to include the list price of prescription medicines in television commercials.

The case is State of Minnesota v. Sanofi-Aventis U.S. LLC, et al, U.S. District Court, District of New Jersey, No. 18-cv-14999.

Reporting by Nate Raymond in Boston; Editing by David Gregorio and Bill Berkrot

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Exhibit F

The New York Times https://www.nytimes.com/2019/02/26/us/politics/prescription-drug-prices.html

Drug Makers Try to Justify Prescription Prices to Senators at Hearing

By Robert Pear
Feb. 26, 2019

WASHINGTON — Pharmaceutical executives, testifying before Congress, could not readily explain on Tuesday why the prices for many brand-name prescription drugs were much higher in the United States than in other developed countries.

“It is almost as if the taxpayer has ‘stupid’ written on their face,” Senator Bill Cassidy, Republican of Louisiana, told the seven executives, who faced a barrage of questions and criticism at a three-hour hearing of the Senate Finance Committee.

Mr. Cassidy joined two other Republican senators, Charles E. Grassley of Iowa and John Cornyn of Texas, and all the Democrats on the panel in expressing deep concern about constituents who could not afford the drugs they needed to survive.

Senator Robert Menendez, Democrat of New Jersey, the home to many drug and biotechnology companies, offered what he described as “a friendly warning” to the witnesses. “If you don’t take meaningful action to reduce prescription drug prices,” he said, “policymakers are going to do it for you.”

The hearing was political theater, but could also be a first step toward legislation to provide some relief to consumers, as lawmakers of both parties and President Trump have vowed to slow the relentless rise of drug prices.

It was also clear from the hearing that senators had a lot to learn about drug pricing and that pharmaceutical executives did not fully appreciate the explosive political potential of the issue.

“I feel like I need a Ph.D. in prescription drug pricing to understand how the heck this industry works,” said Senator Maggie Hassan, Democrat of New Hampshire.

Richard A. Gonzalez, the chairman and chief executive of AbbVie, the maker of the best-selling arthritis drug Humira, told the committee that his company made profits in countries like Germany and France where prices of brand-name drugs were often much lower than in the United States.

“The U.S. has some of the highest prices in the world,” Mr. Gonzalez said.

Senator Ron Wyden of Oregon, the senior Democrat on the committee, asked, “How is that not gouging American consumers with high prices?”

“You’re willing to sit by and hose the American consumer while giving price breaks to consumers overseas,” Mr. Wyden said. Drug makers’ attempts to justify their prices, when so many patients cannot afford them, are “morally repugnant,” he said.

The drug makers vehemently opposed Mr. Trump's proposal for Medicare to pay for certain prescription drugs based on the prices paid in other developed countries.

The Trump administration has said Medicare is paying 80 percent more than the amount other advanced industrial countries do for some of the most costly physician-administered drugs. Under its proposal, Medicare would still pay 26 percent more.

But the drug company executives bristled at the idea. Under such proposals, they said, the United States would be importing price controls from other countries where coverage of costly new drugs is sometimes delayed or denied.

"American patients have access to cancer medicines about two years earlier than patients in other countries, including Germany, France and the United Kingdom," said Pascal Soriot, the chief executive of AstraZeneca. As a result, he suggested, American patients have generally seen greater improvements in cancer survival rates.

Kenneth C. Frazier, the chief executive of Merck, said his company could not just walk away from European markets where health officials set lower drug prices. It would be "immoral to leave the patients behind," he said.

Mr. Cornyn said AbbVie had tried to block competition for Humira by surrounding it with a thicket of patents. In response to questions, Mr. Gonzalez, the chief executive, said AbbVie had 136 patents on Humira, with different patents protecting its use to treat different conditions.

"I support drug companies' recovering a profit based on their research and development of innovative drugs," Mr. Cornyn said. "But at some point that patent has to end, that exclusivity has to end, so that patients get access to those drugs at a much cheaper cost."

Mr. Cassidy expressed interest in an idea that has been embraced by many Democrats but few Republicans: that Medicare should, in some cases, be able to negotiate prices with drug manufacturers.

"Right now," Mr. Cassidy said, "Medicare has a very limited ability to negotiate" prices based on the relative value of a therapy. Medicare's prescription drug plans, offered by private insurers, hire pharmacy benefit managers to negotiate, but they are not always effective, he said.

Senator Sherrod Brown, Democrat of Ohio, said taxpayers subsidized pharmaceutical research, through the National Institutes of Health, and advertising, through tax deductions for business expenses. But, he noted, many drugs cost more than the median income of Medicare beneficiaries, about $26,000 a year.

"We can't afford to gave Big Pharma the blank check that you've had," Mr. Brown told the executives.

Mr. Grassley, the committee chairman, set the tone for the hearing when he said that practices of the pharmaceutical industry "thwart the laws and regulations designed to promote competition" and the use of lower-cost generic drugs.

Several themes ran through the testimony of the drug company executives, who were clearly playing defense. The main problem, they said, is not the high list prices set by drug manufacturers, but the high out-of-pocket costs paid by patients.

Several drug company executives suggested establishing a monthly or annual limit on a Medicare patient's out-of-pocket costs for prescription drugs.

Several chief executives, including Mr. Frazier of Merck and Olivier Brandicourt of Sanofi, said they could also support legislation that speeds the development of generic medications by requiring brand-name manufacturers to provide samples to generic drug companies. Generic drug developers need samples to show that a generic copy is equivalent to the original, but they have often had difficulty getting them.

Ronny Gal, a securities analyst who follows the drug industry for Sanford C. Bernstein & Company, said he doubted that drug companies would change their pricing practices because of the hearing.

“This is a $460 billion industry,” Mr. Gal said. “You think three hours of an orchestrated show before Congress will lead to different behavior? I don’t think so.”

Pharmaceutical executives do “want to be at the table for whatever comes next,” Mr. Gal said, and that could eventually include discussions and negotiations on legislation.

Mr. Gonzalez, of AbbVie, said drug prices were a problem for some patients because their out-of-pocket costs were often a percentage of a drug’s list price.

Mr. Soriot said the list prices of drugs did not reflect the true cost because AstraZeneca and other companies provided rebates and discounts to many health insurance plans and the middlemen known as pharmacy benefit managers. On average, he said, the rebates — intended to secure a favored position on a health plan’s list of covered drugs — are “nearly 50 percent of our gross revenues in the United States.”

AbbVie, AstraZeneca and several other companies said they would reduce prices for consumers if Congress outlawed the rebates that drug makers pay to insurers and middlemen to promote the use of their drugs in Medicare and commercial insurance.

Democratic senators wanted a firmer commitment. They asked the drug company executives to put it in writing.

Albert Bourla, the chief executive of Pfizer, said he supported efforts to eliminate rebates paid to health plans and middlemen. Patients, he said, should get the benefit of such price concessions at the pharmacy counter.

“None of the close to $12 billion of rebates that Pfizer paid in 2018 found their way to American patients,” Mr. Bourla said.

He also said drug makers should be paid in proportion to the value of their medicines. Pfizer, he said, could be “paid based on the number of strokes we prevent or the number of cancer patients who go into full remission, rather than the number of pills we sell.”

With the proliferation of high-deductible health plans, Mr. Bourla said, patients are paying a larger share of prescription drug costs.

“Patients are made to pay on average 14 percent of the cost of their medicines, but only 3 percent of the costs associated with hospital stays,” he said.

Patients, doctors and members of Congress have cited rising insulin prices as an example of what is wrong with drug prices in America, and Mr. Brandicourt, the Sanofi chief executive, defended the company’s record.

“The net price of our insulin product Lantus has fallen over 30 percent since 2012,” Mr. Brandicourt said. “Yet over this same period, average out-of-pocket costs for patients with commercial insurance and Medicare — before the benefit of any Sanofi financial assistance program — has risen 60 percent.”

A version of this article appears in print on , Section B, Page 6 of the New York edition with the headline: Drug Makers Try to Justify Higher Costs at Hearing

Exhibit G

Shots

HEALTH INC.

Pharmaceutical Company CEOs Face Grilling In Senate Over High Drug Prices

FEBRUARY 26, 2019 · 1:24 PM ET

By Alison Kodjak

Sen. Ron Wyden, D-Ore., left, and Sen. Chuck Grassley, R-Iowa, right, chairman of the Senate Finance Committee, asked drug company CEOs some tough questions about drug prices on Tuesday during a hearing before the Senate Finance Committee.

Pablo Martinez Monsivais/AP

The leaders of seven drug industry giants were forced to defend their industry's prices and business practices on Capitol Hill on Tuesday, as lawmakers criticized them for failing to put patients before profits.

"Prescription drugs did not become outrageously expensive by accident," said Sen. Ron Wyden, D-Ore. "Drug prices are astronomically high because that's where pharmaceutical companies and their investors want them."

The pharmaceutical company leaders, testifying at a hearing of the Senate Finance Committee, acknowledged that their prices are high for many patients, but they deflected blame onto the insurance industry, government and middlemen known as pharmacy benefit managers.

They each acknowledged briefly that they have some role to play in helping lower drug prices. But they defended their industry by touting their multibillion-dollar investments in research and development and praising advances in treatments for cancer, hepatitis C, schizophrenia and autoimmune diseases.

"Last year, Janssen invested $8.4 billion globally in research and development, making Janssen one of the top research and development investors in any industry anywhere in the world," said Jennifer Taubert, worldwide chairman of pharmaceuticals for Johnson & Johnson, which owns Janssen.

The drug industry leaders also pointed out that the list prices they set for drugs are not what they are actually paid by insurance companies or pharmacy benefit managers, the middlemen that negotiate discounts and rebates on behalf of employers or insurers, which include companies like CVS Caremark and Express Scripts.

"We want these rebates, which lower net prices, to benefit patients," said Olivier Brandicourt, CEO of Sanofi, which makes Lantus, one of the highest priced brands of insulin, whose list price has risen from $244 to $431 since 2013, according to the committee.

"Unfortunately, under the current system, savings from rebates are not consistently passed through to patients in the form of lower deductibles, co-payments or coinsurance amounts," Brandicourt said in testimony prepared for the hearing.

According to investment research firm SSR Health, the net price of Lantus hasF declined 28 percent over the last two years because of those discounts andF rebates.

"Addressing list prices alone will not be sufficient for solving the problem ofF patients' out-of-pocket costs," Brandicourt said.

But the Senators had little patience for those arguments.

"For a patient taking a drug that has no competition, the list price becomes veryF important," said Sen. Chuck Grassley, R-Iowa, the committee's chairman. "I'veF heard about people skipping doses of their prescription drugs to make them lastF until the next paycheck."

Wyden piled on.

"I think you and others in the industry are stonewalling on the key issue, which is actually lowering list prices," he said. "Lowering those list prices is the easiest way for consumers to pay less at the pharmacy counter."

Many patients have to pay the full price for a prescription drug until they meet their deductible, and others have payments that are calculated as a percentage of the list price. So higher list prices often translate to higher costs at the pharmacy counter, even when pharmacy benefit managers and insurers have negotiated discounts.

Several of the drug company leaders said they support a Trump administration proposal to change the current system in which drug prices are set using secret rebates negotiated by pharmacy benefit managers.

The change would make those rebates illegal and force pharmacy benefit managers to instead negotiate discounts upfront so that people will get the discounts at the pharmacy counter even if they haven't yet met their deductible.

Several of the CEOs, under pressure from Grassley, said they would lower their list prices if that proposal is finalized and the rule applied to both government and commercial prescription drug plans.

"It is our very clear intention that we will not keep a single dollar from these rebates. We will try to move every single penny to the patients," said Albert Bourla, CEO of Pfizer.

Taubert of Johnson & Johnson said the company's final price would depend on whether additional fees were imposed by pharmacy benefit managers.

However, they said they don't want to see the government negotiating drug prices directly through Medicare, a proposal that has been brought forward by Democrats and was originally embraced by President Trump.

"The government should not directly control the price of medicines either through federal government price controls or worse, outsourcing prices to other countries," Brandicourt said.

Even as the companies protest that the high list prices of their products don't reflect what they actually make on those products, drugmakers have consistently enjoyed some of the highest profit margins of any industry.

Pharmaceutical manufacturers' profit margins have exceeded 26 percent for the last three years and 22 percent for the past 10 years, according to a presentation by CVS Health that cited Macrotrends.net as its source.

The company executives were not supportive of another Trump proposal to tie the price that Medicare pays for drugs to the prices paid in other developed countries.

"We need an American solution to this American challenge," said Taubert of Johnson & Johnson's Janssen unit.

Wyden grilled Richard Gonzalez, CEO of AbbVie, about why his company's drugs cost on average 40 percent less in Germany and France than in the United States. (AbbVie makes the drug Humira, which generates about $18 billion in revenue for the company each year.)

"You've got a double standard," Wyden said. "You're willing to sit by and hose the American consumer and give the breaks to people overseas."

Gonzalez acknowledged that the company makes a profit in those countries, even with the lower prices, but warned of dire consequence if U.S. prices fell to those levels.

"If a market the size of the U.S. were to collapse to the lower end of that pricing model, I can just tell you that AbbVie would not be able to invest in the level of R & D that it invests in today," Gonzalez said.

In response to a question from Grassley, all the CEOs said they consider the risk of negative public opinion when they decide on their list prices. The Trump administration has proposed requiring companies to include their drugs' list prices in all their direct-to-consumer advertising, a plan the companies have resisted.

They also said they consider the reaction of federal officials to their price announcements.

"The federal government is a very key aspect of our deliberations," said Pascal Soriot of AstraZeneca, an answer echoed by all seven industry leaders.